c.) Remarks

The subject matter of original claim 2 is represented as claims 2 and 48-50. The subject matter of original claim 23 is presented as claims 23, 53 and 54. Elected (or non-elected) claims 1, 26-28, 32, 34-37 and 39-47 are cancelled without prejudice so as to reduce the issues and expedite prosecution.

Claims 3-5, 8-14, 16-20, 23, 25, 29-31, 33 and 38 are amended to maintain their dependency and/or for better idiomatic format. Rejoinder of withdrawn claims 14-25, 29-31, 33 and 38 (directed towards methods of making, or using, the subject matter of elected Group I) is respectfully requested upon allowance of an antecedent elected claims.

The Examiner indicates that "Applicant is required to comply with the sequence rules by inserting the sequence identification numbers of all sequences recited within the claims and/or specification" and further states that Applicant has not provided sequence identifiers in the specification at page 61, 66 or table 4. In response, Applicants have amended the specification to include sequence identifiers and submit a substitute sequence listing in paper and computer readable form. The content of the computer readable form and the Sequence Listing filed herewith are the same. No new matter has been added.

The Examiner has rejected claims 7 and 8 under 35 U.S.C. § 112, first paragraph, stating that the invention appears to involve novel vectors which are essential to the claimed invention. The Examiner contends that the claimed plasmid sequences are not fully disclosed and that the vectors were not obtained by a repeatable process. The Examiner indicates that if the deposit was made under the terms of the Budapest Treaty,

then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon issuance of the patent, would satisfy the rejection. Applicants wish to point out that the papers submitted when the application was filed clearly indicate that the deposit was made under the Budapest Treaty. The papers are attached hereto for the Examiner's convenience. However, to be fully responsive, Applicants undersigned attorney hereby states that the strain has been deposited under the Budapest Treaty and will be irrevocably and without restriction or condition released to the public upon the issuance of the patent.

The Examiner has also rejected claims 1-4 under 35 U.S.C. § 112, first paragraph, contending that "the specification, while being enabling for a polypeptide of SEQ ID NO:1, or the amino acid sequence comprising amino acids 31-310 of SEQ ID NO:2 and having β 1,3 galactosyltransferase activity, does not reasonably provide enablement for such a polypeptide from any or all sources and for any variants, mutants or recombinants having the same activity. Applicants respectfully disagree.

However, in order to advance prosecution of the present application, Applicants have cancelled claim 1 and written claim 50 so as to obviate the Examiner's concerns. As such, claim 50 is directed to a polypeptide in which up to 20 amino acids have been deleted, replaced or added and having β 1,3 galactosyltransferase activity capable of sythesizing Gal β1-3GlcNAc structure. The subject matter of this language is

found in the specification as filed, *inter alia*, at page 5, lines 7-23 and page 21, line 7 to page 35, line 36.

The Examiner rejected claims 5-13, 26 and 27 under 35 U.S.C. § 112, first paragraph alleging that "the specificaiton, while being enabling for DNA with SEQ ID NO:2 or DNA consisting of nucleotide 402 to 1331 or 492-1331 encoding a polypeptide with β 1,3 galactosyltransferase activity , does not provide enablement for any and all DNA encoding such a polypeptide. While Applicants respectfully disagree. However, in order to advance prosecution of the present application, Applicants have amended the claims in conformity with the Examiner's comments.

The Examiner also rejected claims 1-13, 26 and 27 under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the invention at the time of filing. Specifically, the Examiner contends that claims 1-4 are directed to polypeptides having β 1,3 galactosyltransferase activity and that the specification does not describe all of the polypeptide sequences encompassed by the claims. The Examiner further alleges that applicants have only provided characterization of SEQ ID NO:1 and not of the claimed genus and has not described the structure of

sequences, including fragments and variants, within the scope of the claimed genus. Applicants respectfully disagree.[1/]

As noted above, however, in order to advance prosecution of the present application, as noted above, Applicants have cancelled claim 1 and rewritten claim 2. In view of the amendment, the scope of claims 2-4 is fully commensurate with the description in the application as filed and Applicants respectfully request withdrawal of the rejection of Claims 1-4 under 35 U.S.C. § 112.

The Examiner rejected claims 1-6, 8-9, 12 and 13 under 35 U.S.C. § 102(b) as anticipated by Hennet et al.(*J. Biol. Sci.* 273:58-65, 1998). The Examiner contends that Hennet et al. disclose three polypeptides, polynucleotide encoding them and transformants, wherein the polypeptides have identical β 1,3-galactosyltransferase activity and which are "variants" resulting from either deletion, addition or replacing one or more amino acids in

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1/ The Examiner has directed Applicants' attention to the Revised Written Description Guidelines published in the Official Gazette. Applicants assert that they have adequately described the polypeptide sequence encompassed by the claims as further indicated below. However, the Written Description Guidelines published in the Official Gazette, do not limit Applicants to the specific DNA sequence disclosed, as the Examiner contends. Reference is made to the Supplementary Information to the Written Description Guidelines in which public comments were addressed (Fed. Reg. Vol. 66, No. 4, pp. 1099-1111 (January 5, 2001). Comment 9 relates to claiming DNA. In the response, it is noted that "describing the complete chemical structure, i.e. the DNA sequence, of a claimed DNA is *one* method of satisfying the written description requirement, but it is not the only method." *Id.* at 1101, *emphasis added.* The response further points out that "an adequate written description of a DNA . . . requires a precise definition, *such as* by structure, formula, chemical name, or physical properties." *Id. emphasis added in original.* The response further states "therefore, there is no basis for a *per se* rule requiring disclosure of complete DNA sequences or limiting DNA claims to only the sequence disclosed." *Id.* Accordingly, it is clear that the USPTO does *not* intend to limit DNA claims to only the sequence disclosed.

SEQ ID NO:1 and/or which polynucleotides are capable of hybridizing to the polynucleotide with SEQ ID NO:2 under stringent conditions.

This rejection is respectfully traversed in view of the foregoing amendment. As presented, claim 50 is directed to polypeptides having up to 20 amino acids deleted, replaced or added. Such polypeptides have 93.5% and 92.3% identity with the polypeptide consisting of the amino acid sequence represented by SEQ ID NO:1 and the polypeptide containing the amino acid sequence of 31 to 310 in the amino acid sequence represented by SEQ ID NO:1, respectively. As described in the specification at page 69, lines 1-10, the polypeptide consisting of the amino acid represented by SEQ ID NO:1 but has 28-37% homology to the three polypeptides described by Hennet et al. Therefore, it is apparent no pending claims encompass the Hennet et al. polypeptides. Accordingly, Applicants respectfully request withdrawal of the rejection of claims 1-6, 8-9, 12 and 13 under 35 U.S.C. § 102(b) as anticipated by Hennet et al.

The Examiner has also rejected claim 26 under 35 U.S.C. § 102(b) as allegedly anticipated by GenBank Accesssion No. AAQ67067, 1995. While Applicants respectfully disagree, this rejection is mooted in view of the above cancellation of claim 26.

The Examiner has rejected claims 10-11 under 35 U.S.C. 103(a) as being allegedly unpatentable under 35 U.S.C. § 103(a) over Hennet et al. and further in view of the common knowledge in the art at the time of filing.

As noted above, Hennet et al. do not disclose polypeptides which fall within the scope of the pending claims as currently amended, or which are structurally obvious

therefrom. Accordingly, Applicants respectfully request withdrawal of claims 10-11, which depend from claim 9, under 35 U.S.C. § 103(a).

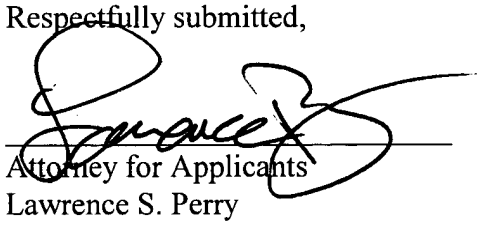
The final remaining matter, therefore, is the rejection of claim 27 under 35 U.S.C. § 103(a) as allegedly unpatentable over GenBank Accession No. AAQ67067, 1995 as applied to claim 26, and further in view of the common knowledge at the time the invention was filed. Again, this rejection is mooted in view of the cancellation of claim 27.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 2-25, 29-31, 33, 38 and 48-52 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,



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